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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/801,180  | 03/15/2004  | John R. Prybella     | 1611/A43            | 3208             |
| 2101  | 7590        | 09/09/2004           | EXAMINER            |                  |
| BROMBERG & SUNSTEIN LLP<br>125 SUMMER STREET<br>BOSTON, MA 02110-1618 |             |                      | RAEVIS, ROBERT R    |                  |
|   |             | ART UNIT             |                     | PAPER NUMBER     |
|   |             |                      |                     | 2856             |

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                             |                     |  |
|------------------------------|-----------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>      | <b>Applicant(s)</b> |  |
|                              | 10/801,180                  | PRYBELLA ET AL.     |  |
|                              | Examiner<br>Robert R. Raevs | Art Unit<br>2856    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 July 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-66 is/are pending in the application.  
 4a) Of the above claim(s) 2-6,11-14,16-19,22,24-39,45-49,53-59,61,62,67-75,64,65 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,7-10,15,20,21,23,40-44,50-52,60,63 and 66 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5-19-04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

Election of Group III is acknowledged.

Claims 15,40 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

How does locating the vent upstream of the sample container allow for the container to be filled? The written specification/drawings properly suggests location 118 for the vent/filter; but how does locating it near clamp 130 allow for any purpose?

Claims 1,7-10,15,20,21,23,40-44,50,51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 1, 23, how is "closed" (line 1) accurate? After all, doesn't use of the vent/filter assure that the system is --open--, and thus not "closed"?

As to claim 20, "sampling material" lacks antecedent basis. Should "material" read --chamber--?

As to claim 59, "55" should read --58--.

As to claim 70, this claim is mixing features of two embodiments. Should "69" read --55--?

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,9,20,21,23,43,50,51,52,60,63 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Pratt '302.

Pratt '302 teaches (Figure 1) a system, including: first port 38, sample chamber(s), one way valve (20,20a), and cap 22. Either the cap 22 may be "removed" (col. 3, line 53) to provide for a second port to pour ("is poured" on col. 3, line 53) the contents, or the cap 22 may have an "opening" (col. 3, line 55) to provide for the claimed second port.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,20,21,23,50,51,52,60 are rejected under 35 U.S.C. 102(b) as being anticipated by Kanno.

Kanno teaches (Figure 3) a sampler including: first port (inlet to valve 32), sampling syringe chamber 37, inlet valve 32, outlet port of syringe 37 through which

blood exits when the syringe piston is pushed into the syringe. Also, when used as a pump, it indicates the volume of liquid that is drawn passed ("downstream") the check valve, indicative of fresh sample material.

Claims 7,8,41,42,66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanno.

As to claims 7,8,41,42,66, it would have been obvious to employ any known syringe for Kanno's syringe 37. In addition, syringes commonly include indicia indicative of the volume of liquid that enters the syringe, suggestive of use of such a syringe that provides for an indication of volumes of liquid being both moved through the sampling system, and the volume of fluid in the capture volume 35 (including both volume 35 and syringe 37).

Claims 1,9,20,21,23,43,62 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hunkin et al.

See Figure 1, which includes a sample chamber 10 and check valve 19.

Claims 1,20,23,50,52,60 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ryan et al.

Ryan et al teach (Figures 1,2) a sampler chamber 10 with check valve inlet 16, and check valve outlet 23.

Claims 15,44,63 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Pratt or Hunkin et al as applied to claims 1, 43,62 above, and further in view of Robbins.

As to claims 15,44,63, it would have been obvious to employ Robbin's cap and filter 18,21 in either Pratt or Hunkin to preserve the sample immediately after sampling to allow for subsequent analysis.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Greer et al teach a sample container 10 with indicia 62, the combination of which uses a check valve 260. The indicia provides for a determination of concentration, not (claimed) volume.

Jackel et al sample blood with one way valve.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert R. Raevis whose telephone number is 571-272-2204. The examiner can normally be reached on Monday to Friday from 6:30am to 4pm. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosen

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